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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,458	04/13/2000	JAY M. SHORT	DIVER1380-1	5257

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT

PAPER NUMBER

1636

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DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/529,458

Examiner

Konstantina Katcheves

Applicant(s)

SHORT, JAY M.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 22-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48 and 49 is/are allowed.
- 6) ☒ Claim(s) 16-20, 22-33 and 36-45 is/are rejected.
- 7) ☒ Claim(s) 34, 35, 46, 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- 12) ☐ The oath or declaration is required in reply to this Office action.
- If approved, corrected drawings are required in reply to this Office action.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Certified copies of the priority documents have been received in this National Stage.
4. ☐ Certified copies of the priority documents have been received in the International Bureau (PCT Rule 17.2(a)).
5. ☐ Certified copies of the priority documents have been received in the International Bureau (PCT Rule 17.2(a)).
6. ☐ Certified copies of the priority documents have been received in the International Bureau (PCT Rule 17.2(a)).

## Attachments

- 1) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- 2) ☐ The translation of the foreign language is:
- 3) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- 4) ☐ Interview Summary (PTO-413) Paper Notice of Informal Patent Application (PTO-152)

- 1) ☐ Notice of Draftsperson's Patent Drawing (PTO-144) Information Disclosure Statement (PTO-144) Information Disclosure Statement (PTO-144)
- 2) ☐ Notice of Draftsperson's Patent Drawing (PTO-144) Information Disclosure Statement (PTO-144) Information Disclosure Statement (PTO-144)
- 3) ☐ Information Disclosure Statement (PTO-144) Information Disclosure Statement (PTO-144) Information Disclosure Statement (PTO-144)

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### **DETAILED ACTION**

Claims 16-20 and 22-49 are pending in the present application. This Office action is in response to Paper No. 29, filed 17 March 2003 and Paper No. 27, filed 5 December 2003.

### ***Continued Prosecution Application***

The request filed on 5 December 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/529458 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Response to Amendment***

The rejection of claim 48 under 35 USC §112, first paragraph has been withdrawn in view of Applicant's amendment filed 5 December 2003.

The rejection of claims 16-20 and 22-35 under 35 USC §112, 2<sup>nd</sup> has been withdrawn in view of Applicant's amendment filed 5 December 2003.

Claims 16-20, 22-33 and 36-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view of Short et al (WO 97/04077) and Horikoshi for the reasons already of record.

Claims 16-20, 22-32 and 36-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view Stein et al (1996 J. Bact. 178:591-599) and Horikoshi (1995 Curr. Op. in Biotech. 6:292-297), and further in view of Patanjali et al (1991 Proc. Natl.

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Claims 16-20, 22-33 and 36-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view of Short et al (WO 97/04077) and Horikoshi, and further in view of Mendelsohn et al (Curr. Op. in Biotech. 1994 5:482-486).

### ***Response to Arguments***

Claims 16-20, 22-33 and 36-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view of Short et al and Horikoshi. Claims 16-20, 22-32 and 36-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view of Stein et al. and Horikoshi, and further in view of Patanjali et al.

Applicant's arguments have been noted; however, they are not found persuasive. The art rejections are maintained as Applicant's arguments are not persuasive. Applicant argues that a *prima facie* case for obviousness has not been set forth and Erickson et al is deficient as a reference. Applicant's argument regarding the *prima facie* case for obviousness is similar to that set forth in the amendment filed 20 August 2001, which was already addressed and found not persuasive in the rejection mailed 6 November 2001.

Applicant argues that Erickson et al, the primary reference in the art rejections, is deficient. Applicant states that Erickson et al does teach or suggest a molecule from a library generated from a mixed population of organisms and does not teach identification of a third molecule responsible for inhibiting interaction between a first and second molecule wherein all these molecules are encoded by the same nucleic acid source. This is not persuasive as Erickson teaches a method for identifying a molecule that inhibits interaction between a first and second molecule wherein the first and second molecules are encoded by the same nucleic acid source, including genomic libraries.

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Generating a library from a mixed population of organisms is taught by both Stein et al and Short et al. Motivation to use the libraries of mixed populations of organisms in the method of Erickson et al. comes both from the prior art, Horikoshi, and from the knowledge of one of ordinary skill in the art. Furthermore, while Erickson et al does not teach that all three interacting molecules are encoded by the same nucleic acid source, the pending claims are not restricted to that embodiment alone. Therefore, this argument is also not persuasive.

Applicant also argues that Patanjuli et al. does not teach normalization as claimed. It is unclear what exactly Patanjuli et al fails to disclose with respect to normalization of a genomic library. According to Applicant's own arguments on page 11 of their response, normalization includes at least one of the steps of (i) amplification and (ii) recovery of a fraction of the isolated DNA. Applicant points to US Patent 6,001,574 for this definition of normalization. First, Applicant should note that each patent is examined on its own merits and the disclosure of the cited patent is not dispositive of this point. Second, a flowchart of the steps for producing a normalized library is shown in Figure 1 of Patanjuli et al., which includes fractionating isolated nucleic acids, amplifying single stranded nucleic acids and cloning them into lambda gt10, an expression vector. Therefore, this argument is also not persuasive because Patanjuli et al. does teach amplification.

Claims 16-20, 22-33 and 36-45 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Erickson et al in view of Short et al. and Horikoshi, and further in view of Mendelsohn et al. Applicant argues that the inclusion of Mendelsohn et al. fails to cure the

above arguments with regard to Erickson in this Office action and the prior art.

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Mendelsohn is cited for the use of green fluorescent protein as a detectable gene in two hybrid methods used to find compounds that modulate protein interactions. See p. 485, first column. It is not cited for the a method for the identification of molecule from a library generated from a mixed population of organisms and does not teach identification of a third molecule responsible for inhibiting interaction between a first and second molecule.

#### *Allowable Subject Matter*

Claims 34, 35, 46-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 48 and 49 are allowable.

#### *Conclusion*

This is a continuation of applicant's earlier Application No. 09/529458. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** from the mailing date of this action, the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, but, in any event, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be assessed in such an event.

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
May 30, 2003

JAMES K. LEE  
PRIMARY EXAMINER